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APPLICATION NO. FILING DATE		DATE	FIRST NAMED INVENTOR  Klaus Raming	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/715,962	11/17/2000			Mo-5998/LeA-34.074	7971	
157	7590	03/05/2002				
BAYER COI		N	EXAMINER , ,			
PATENT DEPARTMENT 100 BAYER ROAD				BRANNOCK,	BRANNOCK, MICHAEL T	
PITTSBURGI	1, PA 1520:	)		ART UNIT	PAPER NUMBER	
				1646		
				DATE MAILED: 03/05/2002	5	

Please find below and/or attached an Office communication concerning this application or proceeding.



## Office Action Summary

Application No. 09/715,962 Applican(s)

Examiner

Michael Brannock, Ph.D.

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Raming et al.



- The MAILING DATE of this communication appears	on the cover sheet with the correspondence address –
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SETHE MAILING DATE OF THIS COMMUNICATION.	T TO EXPIRE MONTH(S) FROM
- Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.	
<ul> <li>If the period for reply specified above is less than thirty (30) days, a repl be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period</li> </ul>	• • • • • • • • • • • • • • • • • • • •
<ul> <li>communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute</li> <li>Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	cause the application to become ABANDONED (35 U.S.C. § 133).
Status	
1) X Responsive to communication(s) filed on <u>Aug 27, 2</u>	001
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This action	on is non-final.
3) Since this application is in condition for allowance exclosed in accordance with the practice under Ex pa	cept for formal matters, prosecution as to the merits is rte Quayl@35 C.D. 11; 453 O.G. 213.
Disposition of Claims	
4) 🔀 Claim(s) <u>1-8, 10-17, and 26-38</u>	is/are pending in the applica
4a) Of the above, claim(s)	is/are withdrawn from considers
5)	is/are allowed.
6)	is/are rejected.
7)	is/are objected to.
8) 🗓 Claims <u>1-8, 10-17, and 26-38</u>	are subject to restriction and/or election requiren
Application Papers	
9) The specification is objected to by the Examiner.	
10) The drawing(s) filed on is/ai	e objected to by the Examiner.
11) The proposed drawing correction filed on	is: al approved b) □disapproved.
12) The oath or declaration is objected to by the Examine	r.
Priority under 35 U.S.C. § 119	
13) Acknowledgement is made of a claim for foreign prior	ity under 35 U.S.C. § 119(a)-(d).
a) ☐ All b) ☐ Some* c) ☐None of:	
1. Certified copies of the priority documents have to	
	een received in Application No
<ol> <li>Copies of the certified copies of the priority docu application from the International Bureau *See the attached detailed Office action for a list of the c</li> </ol>	(PCT Rule 17.2(a)).
14) Acknowledgement is made of a claim for domestic pri	
Attachment(s)	
15) Notice of References Cited (PTO-892)	18) Interview Summary (PTO-413) Paper No(s).
16) Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:

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## **DETAILED ACTION**

## Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, drawn to polypeptides, classified in class 530, subclass 350.
  - II. Claims 3-8, 10-13, 26-32, drawn to polynucleotides, vectors, host cells and methods of producing a polypeptide, classified in class 536, subclass 23.5.
  - III. Claim 14, drawn to antibodies, classified in class 530, subclass 388.12.
  - IV. Claims 15-17, 33, drawn to transgenic animals, classified in class 800, subclass 3.
  - V. Claims 34 and 37, as claim 37 relates to methods of identifying agonists and antagonists, drawn to methods of identifying agonists and antagonists of a GABAB receptor, classified in class 435, subclass 7.21.
  - VI. Claims 35, drawn to methods of identifying binding partners of a GABAB receptor, classified in class 436, subclass 501.
  - VII. Claims 36 and 37, as claim 37 relates to methods of identifying regulators of gene expression, drawn to methods of identifying regulators of gene expression, classified in class 435, subclass 69.1.
  - VIII. Claim 38, drawn to methods of killing insect pests, classification dependent on the chemical identity of the pesticide.
- 2. The inventions are distinct, each from the other because of the following reasons:

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Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-IV are directed to products that are distinct both physically and functionally, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group II can be used other than to make the protein of Group I, such as in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Additionally, although the antibody of Group III can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods. Although the DNA of Group I can be used to make the transgenic animal of Group IV, the DNA can be used in other materially and functionally distinct methods, such as in gene therapy or as a probe in nucleic acid hybridization assays. Finally, the protein of Group I and the antibody of Group II are not required to make the transgenic animal of Group IV.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is

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deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups V-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group V requires a functional assay of a GABAB receptor, which is not required by any of the other groups. Group VI requires a ligand binding assay of a GABAB receptor, which is not required by any of the other groups. Group VII requires an assay of gene expression, which is not required by any of the other groups. Group VIII requires an insecticidal assay, which is not required of any of the other groups.

The polypeptides of Group I are related to the methods of Groups V, VI, and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I are patentably distinct from each of the methods of Groups V, VI, and VIII because the polypeptides of Group I can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V, VI, and VIII are materially and functionally distinct from the others. Furthermore, the polypeptides of Group I and the method of Group VII are patentably distinct because one is not required for the use of the other.

The polynucleotides of Group II are related to the methods of Groups V-VII as product and process of use. In the instant case the polynucleotides of Group II are patentably distinct

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from each of the methods of Groups V-VII because the polynucleotides of Group II can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V-VII are materially and functionally distinct from the others. Furthermore, the polynucleotides of Group II and the methods of Group VIII are patentably distinct because one is not required for the use of the other.

The antibodies of Group III are related to the methods of Groups V-VIII as product and process of use. In the instant case the antibodies of Group III are patentably distinct from each of the methods of Groups V-VIII because the antibodies of Group III can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V-VIII are materially and functionally distinct from the others.

The transgenic animals of Group IV are related to the methods of Groups V, VII and VIII as product and process of use. In the instant case the transgenic animals of Group IV are patentably distinct from each of the methods of Groups V, VII and VIII because the transgenic animals of Group IV can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V, VII and VIII are materially and functionally distinct from the others. Furthermore, the transgenic animals of Group IV and the methods of Group VI are patentably distinct because one is not required for the use of the other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue

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burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

3. Claims 1-8, 10-17, and 26-38 are generic to a plurality of disclosed patentably distinct species comprising a polypeptide of either SEQ ID NO: 2, 4, or 6, or a polynucleotide of either SEQ ID NO: 1, 3, or 5. Each SEQ ID NO represents a structurally and functionally distinct molecule, the use of one not being required for the use of any other. Further, although a search of one SEQ ID NO may overlap that of another, no two searches would be coextensive, and nor could one search be relied upon to provide art that is anticipatory or might render obvious any other SEQ ID NO; and to search all species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, such species being appropriate to the Group chosen, e.g. if Group I is chosen then an appropriate species would be SEQ ID NO: 2, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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4. Applicant is advised that the reply to this requirement to be complete must include an

election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the

fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The

examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m.

The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal

communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

March 3, 2002

YVONNE EYLER, PH.D SUPERVISORY PATENT EXAMINER

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